

REMARKS

Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the remarks herewith.

**THE REJECTION OF ALL PENDING CLAIMS
UNDER THE JUDICIALLY CREATED
DOCTRINE OF OBVIOUSNESS-TYPE
DOUBLE PATENTING IS OVERCOME**

Claims 1 to 4, 6 to 10, 12 and 13 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512 in view of Bergstrom U.S. Patent No. 5,523,089 or SN Cohen¹. A finding of obviousness-type double patenting turns on whether the invention defined in a claim in the application in issue is an obvious variation of the invention defined in a claim in a prior patent. *See, e.g., In re Berg*, 46 U.S.P.Q.2d, 1226 (Fed. Cir. 1998). In order for an obviousness-type double patenting rejection to stand, the Examiner must show that the claims in issue are obvious based solely on the claims in the prior patent; the disclosure in the prior patent may not be used as prior art. Furthermore, any obvious-type double patenting rejection should make clear: (1) the differences defined by the conflicting claims; and, (2) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

The Federal Circuit applies a two-way analysis to determine whether an obviousness-type double patenting should stand: "the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the [application], and vice versa." *Carman Industries v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983).

Clearly such a test fails in the instant situation because the subject matter of the claims of the '512 patent would not have been obvious from the subject matter of the instant claims, and *vice versa*. Hindsight is necessary for the rejections the Examiner has made, which is impermissible by the nature of obviousness-type double patenting.

The pending claims in the instant application are directed to a method of inducing an immunological response by mucosally administering substantially pure OspA. The Examiner

¹ Previously, claims 1-3 and 7 of U.S. Patent No. 5,688,512 were employed in such a rejection. By that rejection having not been repeated, it is deemed withdrawn and that the Examiner concurs that those claims are patentably distinct from present claims.

alleges these claims are obvious over claim 2 of U.S. Patent No. 5,688,512 Bergstrom U.S. Patent No. 5,523,089 or SN Cohen.

Claim 2 of the '512 patent is directed to a method of inducing a **protective** immunological response by administering substantially pure OspA; and while the administration can be by any route, no particular route of administration is specified in claim 2 of the '512 patent. Thus, there is nothing in the disclosure of claim 2 of the '512 patent that teaches or suggests **the particular mucosal administration** of substantially pure OspA to produce the **generalized** immunological response claimed in the instant application

As shown in diagram 1 immediately below, the commonality between these two methods (administration to elicit a protective immune response v. mucosal administration to elicit any immunological response) is minimal and one does not teach or suggest the other.

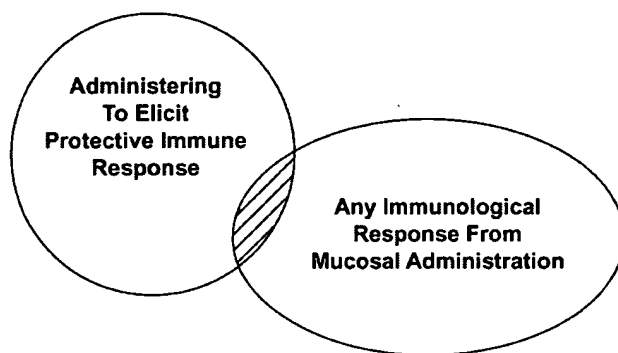


Diagram 1

More in particular, the present claims relate to a method for inducing an immunological response comprising **mucosally** administering a composition comprising substantially pure OspA; e.g., **orally** administering a composition comprising substantially pure OspA. The Office

Action has failed to demonstrate how the generic claims of U.S. Patent No. 5,688,512, in and of themselves (since the specification of U.S. Patent No. 5,688,512 is unavailable to make the double patenting rejection) in any way particularly teach or suggest either mucosal administration or oral administration, or administration for inducing an immunological response as opposed to a protective immune response.

The fact that U.S. Patent No. 5,688,512 claims a method for inducing a protective immunological response comprising administering a vaccine comprising substantially pure OspA is of no moment. It is incumbent upon the Examiner to show how and why oral and mucosal administration are obvious from the generic recitation of "administering" in the claims of U.S. Patent No. 5,688,512. For instance, why and how from just the claims of U.S. Patent No. 5,688,512 should one select oral or mucosal administration as opposed to intradermal, subcutaneous, intracutaneous, intramuscular, and all of the other ways one can "administer" substantially pure OspA, especially considering that the typical way a vaccine is administered is by injection, and not by oral or mucosal routes.

It is also incumbent upon the Examiner to show how and why oral and mucosal administration for any immunological response is obvious from the recitations of generically administering to achieve a protective immune response, again considering all the possible ways to administer an antigen, that injection is the typical route of administration, and a protective response is of different scope than an immunological response.

Having failed to so demonstrate, *inter alia*, why one should select oral or mucosal administration from all of the ways one can administer OspA based upon only the text of the claims of U.S. Patent No. 5,688,512, the obviousness-type double patenting rejection is fatally defective and cannot stand.

The fact that the claims of U.S. Patent No. 5,688,512 may dominate some embodiments of the present claims (and the fact that claims of the present application, when issued, may cover some embodiments within claims of the '512 patent) **is not controlling**. *In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986) ("**there must be some clear evidence to establish why the variation [between claims of a patent and of the application] would have been obvious [for double patenting rejection] which can properly qualify as 'prior art' ... if obviousness predicated on the level of skill in the art, prior art evidence is needed to show what that**

level of skill was"; and only claims of patent or patent application, not its disclosure, are available for use in double patenting rejection).

Any dominance of the presently claimed subject matter by the claims of U.S. Patent No. 5,688,512 and any coverage of '512 patent subject matter by the present claims, when issued, is not controlling in determining double patenting. *In re Kaplan*, 229 U.S.P.Q. at 681 ("**This commonplace situation [of one patent dominating another] is not, per se double patenting as the board seemed to think**"). It is respectfully submitted that contrary to *In re Kaplan*, the Examiner is equating dominance with double patenting; and thus, the rejection is improper.

In further support of the proposition that U.S. Patent No. 5,688,512 can claim a genus which dominates some embodiments of the present claims while the present claims still remain patentably distinct, the Examiner is respectfully reminded that a species (or subgenus) may be patentably distinct from a genus such that a first patent issues to one party with claims directed to the genus, and a second patent issues to another party with claims directed to the species or subgenus. *See e.g., In re Baird*, 29 USPQ 2d 1550 (Fed. Cir. 1994); *In re Jones*, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Taub, Wendler, and Slates*, 146 USPQ 384 (C.C.P.A. 1965); *In re Petering*, 133 USPQ 275 (C.C.P.A. 1962); *Hsing v. Myers*, 2 USPQ2d 1861 (BOPAI 1987).

The Commentary to Rules of Practice, 49 Fed. Reg. 48416, 48433 (Dec. 12, 1984), 1050 O.G. 395 (Jan. 29, 1985), corrected to 50 Fed. Reg. 23122 (May 31, 1985), 1059 O.G. 27 (Oct. 22, 1985), provides in pertinent part:

Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus. Compare *In re Taub*, 348 F.2d 556, 146 USPQ 384 (C.C.P.A., 1965).

In this regard, the Examiner's attention is also directed to *In re Sasse*, 207 U.S.P.Q. 107 (C.C.P.A. 1980), wherein the Court of Customs and Patent Appeals held that a claim to a genus and a claim to a species within the genus are not claims to the same or substantially the same subject matter in the sense of 35 U.S.C. §135(b).

Essentially, if the present Applicants were strangers to the inventive entity of U.S. Patent No. 5,688,512 (but had the same effective filing date thereof of October 1988), the PTO would not declare an interference between the present application and U.S. Patent No. 5,688,512 because the claims of the present application and of U.S. Patent No. 5,688,512 would be deemed patentably distinct: the claims of U.S. Patent No. 5,688,512 being directed to a particular genus; and the present claims being directed to a patentably genus or distinct subgenus or species

(especially since there is nothing in the art, as of the October 1988 effective filing date of the present application, in any way teaching or suggesting oral or mucosal administration of OspA). The fact that the genus claims of U.S. Patent No. 5,688,512 dominate some embodiments of the present claims and that the present claims may cover some embodiments within the '512 patent, is of no moment.

The secondary references cited by the Examiner do not supply that for which the Examiner has cited them, and they fail to supply the deficiencies acknowledged by the Examiner.

Firstly, Bergstrom – or the text of U.S. Patent No. 5,523,089 – is not available to the Examiner to use in an obviousness-type double patenting rejection. Bergstrom is related to U.S. Patent No. 5,688,512, as both Bergstrom and U.S. Patent No. 5,688,512 are children of the same original U.S. and Danish applications. To allow the Examiner to rely upon the text of Bergstrom when he cannot rely upon the text of U.S. Patent No. 5,688,512 would render the directives of the case law (such as *Kaplan, supra*) hollow. Thus, the Office Action improperly relies upon Bergstrom, U.S. Patent No. 5,523,089 in making the rejection. Furthermore, to choose the presently claimed subject matter from the text of Bergstrom requires improper hindsight gleaned from the present application and claims.

Secondly, SN Cohen does not teach or suggest oral or mucosal administration of OspA; and is thus no better than the general teachings one finds in the broad, generic claims of U.S. Patent No. 5,688,512. From the entire universe of routes of administering vaccines, one must still select mucosal and oral administration from SN Cohen – a choice that also requires selective hindsight gleaned from the present application and the present claims; and such selective hindsight gleaned from the present application and the present claims is improper. And, SN Cohen does not direct the skilled artisan to oral or mucosal administration of OspA. Thus, SN Cohen does not direct the skilled artisan to the present invention, and does not supply that for which it is cited.

The Examiner is respectfully requested to reconsider the double patenting rejection with the following in mind.

First, it is well established that "there must be some reason for the combination other than the hindsight gleaned from the invention itself". *Uniroyal v. Rudkin-Wiley*, 5 USPQ 2d 1434, 1438 (Fed. Cir. 1980).

Second, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the primary reference in the manner suggested by the Examiner. *In re Laskowski*, 12 USPQ 2d 1397, 1399 (Fed. Cir. 1989).

Third, "obvious to try" is not the standard under 35 USC §103. *In re Fine*, 5 USPQ 2d 1596, 1599 (Fed. Cir. 1988).

Further, as stated by the Court in *In re Fritch*, 23 UPPQ 2d 1788, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification."

The secondary references relied upon in the Office Action fail to provide the necessary incentive or motivation for modifying the primary reference; and therefore, the double patenting rejection fails.

Furthermore, the Examiner is respectfully requested to kindly note that the original Examiner, Hazel Sidberry, was prepared to allow this application over the '512 patent; and Examiner Sidberry also was the Examiner on the '512 patent. Deference should be accorded her original decision to allow this case.

Accordingly, reconsideration and withdrawal of the rejection to claims 1 to 4, 6 to 10, 12 and 13 under the judicially created doctrine of obviousness-type double patenting are respectfully requested.

CONCLUSION

In view of the remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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